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Dockets Management Branch, HFA-305 Food and Drug Administration 5630 Fishers Lake, Room 1061 Rockville, MD 20852

RE: Docket No. 02N-0278. "RIN 0910-AC41." Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (68 Federal Register 5428, February 3, 2003)

Dear Dockets Management Branch:

welcomes Tank Terminals Corporation (Hudson) opportunity to provide comments on the "Prior Notice" requirements for Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act (the Act). Under the Act, the Secretary is required to implement final regulations addressing Section 307 by December 12, 2003. After evaluation of the FDA proposal, Hudson submits that it needs significant clarification, particularly in regard to the import notifications required in respect to cargoes arriving on ocean-going vessels. These comments suggest appropriate clarifications to make implementation more effective and less burdensome.

Hudson Tank Terminals Corporation operates a deepwater bulk liquid tank terminal facility. Hudson's bulk liquid storage tank facility is utilized by numerous importers of vegetable, animal and marine fats and oils. Hudson's clients range from producers of these fats and oil substances, domiciled abroad, to U.S. importers who further process these substances for both edible and technical purposes.

The "DRAFT FOOD FACILITY REGISTRATION FORM" defines Hudson's establishment type at Section 9 i.e. Warehouse/Holding Facility.

Proposed "Window" for Notification is Very Restrictive: The proposal for import notification requires that notice be provided by the importer to FDA "no later than noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry." Section 1.286(a). The proposal

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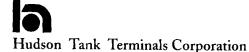
also requires that the importer "may not submit prior notice more than five days before the anticipated date of arrival of the food at the anticipated port of entry." Section 1.286(b). This import notification must be updated if the actual time of arrival is subsequently anticipated to be more than three hours later or one hour earlier than the time of arrival specified in the original notification to FDA. Section 1.294. This language indicates that the anticipated time of arrival at the port of entry is to be stated with great precision in the import notification.

Wider "Window" Needed for Ocean-Going Cargoes: A wider margin of variability should be allowed for the arrival of ocean-going vessels, than is presently provided by the proposal. For ocean-going shipments, an amendment of an importer's import notification should not have to be required so long as the anticipated actual arrival at the port of entry is not more than 24 hours before or after the anticipated time of entry specified in the import notification. This 24 hour allowance takes into account the variability which will be needed in the winter months when vessels are often delayed by storms or high seas or fog. Amended notification should not be required unless the vessel will arrive more than 24 hours before or after the anticipated arrival time specified in the original import notification.

In addition, while the five-maximum day period during which notification can be provided may be reasonable, the proposal should be amended to allow notification to be made within as little as eight hours prior to a vessel's arrival in port.

For Ocean-Going Cargoes, Time of Arrival Is Measured As the Time of Arrival at the Entrance to the Seaport: The proposal's very precise provisions for import notification are not well suited to the arrival of cargoes aboard ocean-going vessels at U.S. seaports. The application of the proposed regulations to cargoes of vegetable oil arriving in ocean-going vessels needs to be clarified. First, it should be clarified that the "time of arrival of the food at the anticipated port of entry" is the time of arrival at the entrance to the seaport at which the importer will be taking delivery. It is at this point that the vessel becomes subject to the control and regulation of U.S. Customs, and the time of arrival at this point, rather than the time of arrival at the importer's dock, should be provided in the import notification.

FDA Requirements Should be Harmonized with Those of the U.S. Customs Service: Finally, FDA's import notification procedures should be harmonized with those of the Delivery Authorization Documents filed with the U.S. Customs Service. These documents provide substantially the same information which will be required in FDA's notifications and include a uniform manufacturer



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identification number. Not only will the failure to harmonize the requirements of FDA and Customs be burdensome on importers, but also it will result in a loss of clarity and efficiency in the programs of both FDA and Customs.

Thank you for your consideration of these comments.

Respectfully Submitted,

hogen

A. F. Mogerley

President

AFM/el